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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17BZ]

[Docket No. CDC-2016-0104]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project entitled "Project Pride." This project is funded by CDC at 12 health departments in the United States. The health

departments will report standardized program monitoring and evaluation (M&E) data to CDC. CDC is requesting approval to collect standardized HIV prevention program evaluation data from funded health departments.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2017-0104 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to

the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Project PrIDE - New - National Center for HIV/AIDS, Viral

Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

State, local and territorial health departments in the U.S. are implementing high impact HIV prevention programs to reduce new HIV infections among populations of gay, bisexual, and other men who have sex with men (MSM) and transgender persons. Additional effort is needed to realize the benefits of new prevention strategies that have the potential to significantly reduce new HIV infections and increase viral suppression among MSM and transgender persons.

Pre-exposure prophylaxis (PrEP) is a potent new prevention tool for MSM without HIV but who are at substantial risk of acquiring HIV infection. The daily use of oral, antiretroviral medication (PrEP) with co-formulated tenofovir disoproxil fumarate and emtricitabine (marketed as Truvada®) is proven to significantly reduce the risk of HIV acquisition among sexually active adults. In July 2012, the US Food and Drug Administration approved an HIV prevention indication for Truvada, and in May 2014 CDC published Public Health Service clinical practice guidelines for provision of PrEP to persons at substantial risk of HIV acquisition through sexual or injection routes of transmission as part of a package of HIV prevention clinical

services. It is critical for health departments to address barriers to and facilitate broader awareness, support and capacity for the scale-up of PrEP services for MSM and transgender persons at high risk for HIV infection, particularly persons of color, recognizing that the population with the highest incidence of HIV in the U.S. is young African American MSM.

Another potent prevention tool involves antiretroviral medication to suppress HIV-1 viral load, improve health outcomes and reduce transmission risk among people living with HIV (PLWH). The importance of antiretroviral treatment has increased focus on interventions and public health strategies designed to link, engage and re-engage persons living with HIV in health care, with the ultimate outcome of suppressing HIV viral load, decreasing morbidity and increasing survival. To increase viral suppression, more people who are diagnosed with HIV will need to be retained in HIV medical care and receive antiretroviral treatment. There is a need for health departments to implement public health strategies for improving linkage, engagement and re-engagement of MSM and transgender persons who are not in care.

Data to Care is a public health strategy for identifying these individuals. Data to Care is based on the use of surveillance data to intervene directly in disease control. Data

to Care programs use laboratory reports received by a health department's HIV surveillance program, and a range of other data sources as markers of HIV care, and analyze these reports to confidentially identify HIV-diagnosed individuals who are not engaged in HIV medical care or have not achieved viral suppression. Several state health departments have taken steps toward initiating a Data to Care program, and a few have reported successful implementation of Data to Care activities. It is important that these efforts be expanded and that other state, local and territorial health departments scale up and implement this promising public health strategy to improve outcomes along the HIV continuum of care and prevent new HIV infections.

The purpose of this project is to support 12 health departments in the United States to implement PrEP and Data to Care demonstration projects for 200 clients annually, prioritizing MSM and transgender persons at high risk of HIV infection, particularly persons of color.

Health departments that are involved in this project will be required to prioritize their services to these populations. Services may also be provided for persons at substantial risk for HIV (for PrEP) or persons who have HIV and are not virally suppressed or have ongoing risk behavior (for Data to Care) who are not MSM or transgender.

CDC HIV program grantees will collect, enter or upload, and report budget data, information on the HIV prevention and care services, and client demographic characteristics with an estimated of 1,104 burden hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per response (in hours)	Total Burden Hours
Clients	Data Elements	2,400	1	25/60	1,000
Health Departments	Data Management	12	2	20/60	8
Health Departments	Performance Progress Report	12	1	8	96
Total					1,104

Leroy A. Richardson
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 Office of Scientific Integrity
 Office of the Associate Director for Science
 Office of the Director
 Centers for Disease Control and Prevention

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